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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/948,124	10/09/97	REINHERZ E	DFCI-522A

HM22/1026
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EXAMINER	
BANSAL, G	

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 10/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/948,124	Rienhart et al
Examiner	**Group Art Unit**
Geetha P. Bansal	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8/6/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 41, 45, 1-40, 42, 44, 46-52 is/are pending in the application.

Of the above claim(s) 1-40, 42, 44, 46-52 is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 41, 45 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

1. Applicant's amendment filed August 6, 1999 (Paper No:13/B) is acknowledged. The information and attached documents to indicate the copendency of the parent with instant application at its filing has been reviewed and entered. The effective filing date of the present Application is 2/18/97. Claim 43 has been cancelled, claims 41 and 45 are amended. Accordingly, claims 41 and 45 are being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

3. The following rejections are withdrawn:

Rejection of claims 41 and 45 under 35U.S.C. 112, second paragraph is withdrawn in view of the amendments of the claims.

4. Rejection of claims 41, 45 under 103(a) as being obvious over Gurtu et al is withdrawn as Gurtu et al is now established to be after the effective filing date of the instant claims.

5. The following are new rejections:

A. Claims 41 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are indefinite in the recitation of "enhanced caspase or procaspase" as it is not clear if the enhance relates to the activity or expression or levels of the caspase or procaspase.

B. Claims 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnhead et al (1995).

Claims are drawn to a method of identifying an agent that enhances a caspase or procaspase which is expressed in immature thymocytes (wherein the caspase activity is considered to be its ability to function as a protease and also is associated with apoptosis) and a method of enhancing a caspase or procaspase expressed in immature thymocytes by an agent that is identified.

Fearnhead et al teach that ICE-like proteases (also known as caspases) are involved in thymocyte apoptosis (see Abstract; and pages 285-286), as well as methods to detect the activity of the ICE-like proteases (also known as caspases) by using agents that can inhibit their activity.

Fearnhead et al do not teach methods to enhance the levels or activity of caspase or procaspase in the thymocytes or isolated and purified caspases expressed in immature thymocytes. However, it was well known at the time of the invention that apoptosis occurred in thymocyte and played a vital role in thymic selection processes. It was also known that ICE-like proteases were involved in these events in the thymocytes. Thus it would have been prima facie obvious to one of ordinary skill in the art at the time of the claimed invention to substitute in the cell lysate employed by Fearnhead et al other agents that might have the property of enhancing the apoptosis by enhancing the ICE-like proteases (or caspases), since one of ordinary skill in the art would not expect the thymocyte cell lysates not to contain the caspases. One of ordinary skill in the art would not have expected that caspases from these sources to be different if isolated and identified as a caspase- i.e. the caspase of the claims were inherently present in the thymocyte lysate of Fearnhead et al, and were expressed in the thymocytes. The assays taught by Fearnhead et al inherently measured the activity of the caspases. One of ordinary skill in the art would have been motivated to use the same thymocyte lysate system since thymocytes are involved in immune regulation, in self-recognition events and implicated in mechanisms of clonal deletion by apoptotic pathways. The teachings of Fearnhead et al provides the motivation as well as a reasonable

expectation of success that studies of apoptosis in thymocytes could be done using the methods in Fearnhead et al which teach assays to identify agents that can modulate apoptosis and apply the same methods to identify agents that enhance activities of the caspases expressed in the thymocyte lysate.

5. Claims may be allowable if they were amended to be drawn to isolated caspases from immature thymocytes and with an active step of contacting the agent with an isolated caspase included in the claims.

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1642 by facsimile transmission. Papers should be faxed to Group 1642 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell, can be reached on (703) 308-4310.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Geetha P. Bansal

October 19, 1999.

GEETHA P. BANSAL
PATENT EXAMINER